

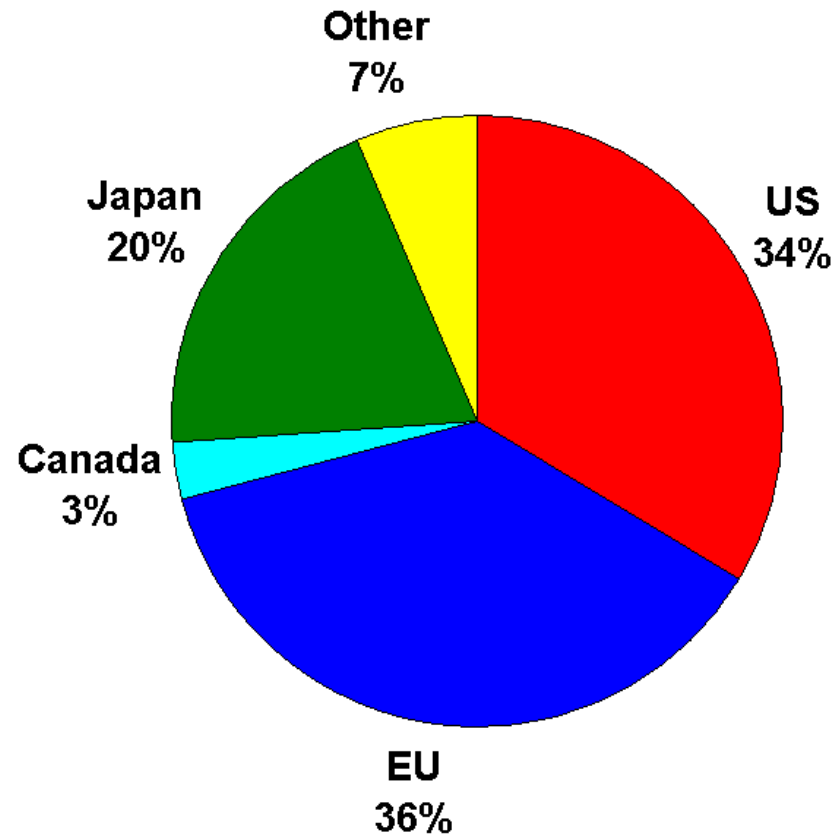


# 10 Year Anniversary

- All this year, the MSSO is celebrating 10 years of MedDRA
  - MedDRA 2.1 released 1 March 1999
- MedDRA has developed into a real standard
- Check our Web site for monthly anniversary activities



# MedDRA Subscriber Update



2471 Subscribers  
Worldwide



# Summary of MedDRA v12.0

- Change request summary:
  - A complex release
  - Released on 1 March 2009
  - MSSO considered 2624 change requests
    - Approved: 1937
    - Rejected: 623
    - Suspended: 64

# Version Report

- All changes are listed in the Version Report

	A	B	C	D
1	<b>Tab Title</b>	<b>Record Count</b>		
2	New LLTs Including New PTs	572		
3	New PTs	285		
4	Promotions	38		
5	Demotions	49		
6	LLT under different PTs	243		
7	LLT (excl PT) Prim SOC Changes	77		
8	PT Primary SOC Changes	20		
9	MedDRA LLT PT Text Changes	2		
10	Currency Changes	10		
11	Hierarchy Changes	24		
12	SMQ Changes	21		
13	PT Changes in SMQs	1189		
14				
15	Move cursor over the report title above to view a description of its contents.			

# Report Sample – New PTs

	A	B	C	D	E	F
1	MedDRA Code	PT	HLT	HLGT	SOC	Primary SOC Flag
2	10068851	Splenic peliosis	Spleen disorders	Spleen, lymphatic and reticuloendothelial system disorders	Blood and lymphatic system disorders	Y
3	10069167	Kounis syndrome	Ischaemic coronary artery disorders	Coronary artery disorders	Cardiac disorders	Y
4	10069140	Myocardial depression	Myocardial disorders NEC	Myocardial disorders	Cardiac disorders	Y
5	10068783	Alstroem syndrome	Retinal disorders congenital	Eye disorders congenital	Congenital, familial and genetic disorders	Y
6	10068841	Cobb syndrome	Vascular anomalies congenital NEC	Cardiac and vascular disorders congenital	Congenital, familial and genetic disorders	Y
7	10069153	Congenital myopia	Ocular disorders congenital NEC	Eye disorders congenital	Congenital, familial and genetic disorders	Y
8	10068850	Cryopyrin associated periodic syndrome	Musculoskeletal and connective tissue disorders of limbs congenital	Musculoskeletal and connective tissue disorders congenital	Congenital, familial and genetic disorders	Y
9	10069098	Cutaneous visceral angiomas with thrombocytopenia	Vascular anomalies congenital NEC	Cardiac and vascular disorders congenital	Congenital, familial and genetic disorders	Y
10						



# Distribution Changes

- Single release zip file includes:
  - ASCII files
  - Release documents
  - Version report spreadsheet
  - SMQ spreadsheet
  - Sequential ASCII files

# Distribution Changes (cont)

- New Release File
  - Meddra\_release.asc
  - Contents of the file describe the language and version of the release
  - Used by updated Desktop Browser
  - Can also be used by subscribers to identify versions
  - No impact to load routines



# WebCR Tool



## MSSO Subscriber Change Request Data Entry (WebCR)

Welcome to the MSSO Subscriber Change Request Data Entry web site. You may submit your MedDRA Change Request to the MSSO here.

### *Verify Subscriber*

Subscriber ID

Password

Login

Cancel

If you have problems logging in, please contact the MSSO Help Desk at [MSSOHelp@ngc.com](mailto:MSSOHelp@ngc.com) OR [1-877-258-8280](tel:1-877-258-8280)

# Change Request Justification

MedDRA®  
MSSO Subscriber Change Request Data Entry (WebCR)

Action ▶ Batch ▶ Retrieve ▶ Preference ▶ Logout

Add a New PT/LLT

Proposed Term (Required)

PT  LLT  Either

Placement Consideration

Justification (Required)

Attachment

Browse...

Save Cancel

- Required to submit a change request
- Needed by MSSO to understand the context of request

# Change Request Justification (cont)

- MSSO will come back to subscribers if the justification provided is not sufficient
- Help the MSSO make the best decision based on the right information

# Change Requests

- Some subscribers seem reluctant to submit changes
  - “Not enough time”
  - “I’m too new”
- How many subscribers have submitted changes ever?
  - How many in the past year?
- MSSO encourages you to make your voice heard

# SMQ Update

- Seven new SMQs added
  - Corneal disorders
  - Eosinophilic pneumonia
  - Hearing and vestibular disorders
  - Retinal disorders
  - Skin neoplasms, malignant and unspecified
  - Thyroid dysfunction
  - Vasculitis
- As of MedDRA v12.0 there are 74 SMQ topics

# SMQ Update (cont)

- SMQs planned for MedDRA 12.1
  - Conjunctival disorders
  - Lacrimal disorders
  - Lipodystrophy
  - Osteoporosis/osteopenia
  - Periorbital and eyelid disorders



# Chinese Translation

- Will be released on 15 September 2009
- Requires fee for Chinese translation subscription
- Has been validated by subscriber volunteers and the MSSO
- MSSO will develop a Chinese page on the MSSO Web site
  - Basic MedDRA information

# Chinese Translation (cont)

- Receive 50% discount on subscription if you subscribe before 15 September

Subscription Levels	2009
Basic	\$100
Core 0 (Annual Revenue/Turnover \$0M - < \$1 Million)	\$100
Core 1 (Annual Revenue/Turnover \$1M - < \$10 Million)	\$200
Core 2 (Annual Revenue/Turnover \$10M - < \$500 Million)	\$500
Core 3 (Annual Revenue/Turnover \$500M - < \$1 Billion)	\$1,000
Core 4 (Annual Revenue/Turnover \$1 Billion - < \$5 Billion)	\$2,000
Core 5 (Annual Revenue/Turnover greater than \$5 Billion)	\$3,000
Developer	\$1,500

# Versioning BRP

- Blue Ribbon Panel (BRP)
  - Goal: develop recommendations on an issue
  - Panel members represent ICH regions
  - Observers play important role
  - MSSO presents recommendations to Board for approval
- Topics of this BRP (13 May 2009)
  - Extent of MedDRA Versioning
  - Frequency of MedDRA releases

# BRP Panel Members

- Barry Hammond (GlaxoSmithKline)
- JoAnn Medbery (Johnson & Johnson)
- Tom Paternoster (European Medicines Agency)
- Toni Piazza-Hepp (US Food and Drug Administration)
- Yasuo Sakurai (Japanese Maintenance Organization)



# Extent of MedDRA Versioning

- Proposed implementation levels

Level	Description
A	Identify verbatim terms linked to non-current LLTs and recode existing data and Recode verbatim terms to new LLTs that are direct or lexical matches and Recode verbatim terms to new LLTs that are medically better matches
B	Identify verbatim terms linked to non-current LLTs and recode existing data and Recode verbatim terms to new LLTs that are direct or lexical matches
C	Identify verbatim terms linked to non-current LLTs and recode existing data
D	Begin to use new version for coding new data; no recoding of existing data



# Frequency of MedDRA Releases

- Can MedDRA be released once a year instead of two times a year?



# Recommendations – Extent of Versioning

1. Content to be added as appendix to “MedDRA Term Selection: Points to Consider” (TS: PTC). PTC WG should further develop content, align it with existing versioning language
2. Add recommendation that organizations document upversioning strategy

# Recommendations – Extent of Versioning (cont)

3. Emphasis on *communication* of version extent; not to be interpreted as regulatory requirement.
4. Include impact, positive and negative, of each method of version updates (e.g., recoding non-current LLTs).

# Recommendations – Feasibility of Annual Release

1. Remain biannual for now; revisit in 2011
2. How to assist small, new subscribers:
  - a. To implement a new version without recoding is acceptable
  - b. Develop tool to assess impact of new version and facilitate upversioning task (MSSO)
  - c. Additional training on version update processes (MSSO)
3. Add to TS: PTC MSSO's recommendation for implementation date/time (00:00 GMT on 1<sup>st</sup> Monday of 2<sup>nd</sup> month after release)

# Recommendations – Feasibility of Annual Release (cont)

4. MSSO to collate the versioning requirements of ICH regulatory authorities and post on MSSO website
5. Regulatory authorities should consider future use of supplemental terms



# Thank You